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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,063	10/10/2001	Jerry S. Powell	500582.12	2666

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DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
SUITE 3400
1420 FIFTH AVENUE
SEATTLE, WA 98101

EXAMINER

MARTINELL, JAMES

ART UNIT	PAPER NUMBER
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1631

8

DATE MAILED: 07/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/975,063	Applicant(s) POWELL, JERRY S.	
	Examiner James Martinell	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: |

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Applicant's election with traverse of the requirement for restriction in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the claims recite a common element and that no serious search burden is imposed upon the USPTO in order to search both Groups I and II. This is not found persuasive because the searches are not coextensive. The polypeptides of claims 34-39 can be made by materially different methods from those of claims 10-33 (*e.g.*, by synthesis or by purification from naturally occurring sources followed by chemical modification). The products of claims 34-39 are thus not defined by the methods of claims 10-33.

The requirement is still deemed proper and is therefore made FINAL.

Claims 34-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no (allowable) generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has not pointed to basis in the application as filed for each and every limitation in newly filed claims 18-33 (see the amendment filed October 10, 2001).

- (a) The recitation of "SEQ ID NO: 1 from position 59 . . . providing for the expression and secretion of the glycoprotein" (claim 18).
- (b) The recitation of "where the host cells are treated with methotrexate" (claim 20).
- (c) The recitation of "methotrexate of about 1 μ M to about 10 mM" (claims 21 and 22).

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- (d) The recitation of "prior to being treated with a second concentration of methotrexate, the second concentration being lower than the first concentration" (claim 22).
- (e) The recitation of "methotrexate is about 1 μ M to about 1 mM" (claim 23).
- (f) The recitation of "metallothionein promoter as the eukaryotic promoter operably linked to the insert" (claim 25).
- (g) The recitation of "at least two million units . . . using a mammalian erythropoietin as a standard" (claim 26).
- (h) The recitation of "wherein the cells are stably transformed" (claims 28 and 29).
- (i) The recitation of "glycoprotein is produced as a level of about 500 to about 7000 units per ml of culture medium . . . and partially purified sheep erythropoietin as a comparative standard" (claim 28).
- (j) The recitation of "glycoprotein is produced at a level of about 6 to about 85 μ g per ml of culture medium" (claim 29).
- (k) The recitation of "an adenovirus-2 major late promoter sequence . . . 3' splice site to provide for the expression and secretion of the glycoprotein into a culture medium" (claim 31).
- (l) The recitation of "metallothionein promoter operably linked to the insert to provide expression and secretion of a glycoprotein into the culture medium" (claim 33).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).


Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-17 and 27-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,688,679 in view of either one of either one of Nimtz et al (Eur. J. Biochem. 213: 39 (1993)) or Yanagi et al (DNA 8 (6), 419 (1989)). Claims 1-6 of U.S. Patent No. 5,688,679 are directed to the same EPO gene fragment as that of the instant claims. Each of the secondary references discloses the production of EPO in mammalian cells in culture (BHK cells). It would have been obvious for one of ordinary skill in the art at the time the invention was made to express the ApaI EPO gene fragment of claims 1-6 of U.S. Patent No. 5,688,679 in either one of the expression systems of the secondary references in order to produce large amounts of EPO.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


James Martinell, Ph.D.
Primary Examiner
Art Unit 1631